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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,140	05/11/2001	Hans H. Schiffer	SALK2940 (088802-8051)	6799

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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/854,140	Applicant(s) SCHIFFER ET AL.	
	Examiner Michael Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a method of detecting the genotype of the kainate receptor subunit GluR7 allele in a subject using , classified in class 435, subclass 6.

II. Claims 14, 15 and 17-19, drawn to a kit comprising an oligonucleotide specific for detecting a kainate receptor subunit GluR7 allele, classified in class 536, subclass 24.31.

III. Claims 14, 16, 20 and 21, drawn to a kit comprising an antibody specific for a kainate receptor subunit GluR7, classified in class 530, subclass 387.1.

IV. Claims 22-28, drawn to a method of treating a subject by administering a compound that alters GluR7 receptor subunit activity or function, classified in unknown class and subclass. The claims do not limit the compound to any specific compound.

V. Claims 29-31, drawn to a method of identifying a compound that alters GluR7 receptor subunit activity, classified in class 435, subclass 325.

VI. Claims 32-36, drawn to a transgenic non-human animal having a knockout of endogenous GluR7 and an insertion of human GluR7, classified in class 800, subclass 8.

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of detecting GluR7 can be performed with oligonucleotides or antibodies. In addition, the oligonucleotides can be used to detect disease, to encode GluR7 or to prevent GluR7 production.

Groups I and III are patentably distinct because the method of detecting the GluR7 allele is used to genotype a subject while the antibody may be used to isolate GluR7 protein. The protocols and reagents required for genotyping are materially distinct and separate than those required for using an antibody. The method of detecting the genotype does not require the antibody and the antibody does not require the method.

Groups I and IV are patentably distinct because the method of detecting the GluR7 allele is used to detect disease while the method of administering a compound may be used to treat disease associated with GluR7. The protocols and reagents required for detecting disease are materially distinct and separate than those required for treating disease. The method of detecting the genotype does not require administering a compound and the method of administering the compound does not require detecting the genotype of GluR7.

Groups I and V are patentably distinct because the method of detecting the GluR7 allele is used to detect disease while the method of contacting a cell expressing GluR7 receptor with a

compound may be used to identify compound capable of treating disease associated with GluR7. The protocols and reagents required for detecting disease are materially distinct and separate than those required for identifying compounds capable of treating disease. The method of detecting the genotype does not require identifying a compound and the method of identifying the compound does not require detecting the genotype of GluR7.

Groups I and VI are patentably distinct because the method of detecting the GluR7 allele is used to genotype a subject while the transgenic non-human animal may be used as an *in vivo* model of disease. The protocols and reagents required for genotyping are materially distinct and separate than those required for making and/or using a transgenic animal. The method of detecting the genotype does not require the transgenic and the transgenic does not require the method.

Groups II and III are patentably distinct because the oligonucleotide is used to detect a nucleic acid sequence while the antibody is used to detect or isolate GluR7 protein. The protocols and reagents required for oligonucleotides and antibodies are materially distinct and separate. The oligonucleotide does not require the antibody and the antibody does not require the oligonucleotide.

Groups II and IV are patentably distinct because the oligonucleotide may be used to detect the GluR7 allele while the method of administering a compound may be used to treat disease associated with GluR7. The protocols and reagents required for using oligonucleotides to detect disease are materially distinct and separate than those required for treating disease. The

oligonucleotide does not require administering a compound and the method of administering the compound does not require the oligonucleotide.

Groups II and V are patentably distinct because the oligonucleotide may be used to detect the GluR7 allele while the method of contacting a cell expressing GluR7 receptor with a compound may be used to identify compound capable of treating disease associated with GluR7. The protocols and reagents required for using an oligonucleotides are materially distinct and separate than those required for identifying compounds capable of treating disease. The oligonucleotide does not require identifying a compound and the method of identifying the compound does not require the oligonucleotide.

Groups II and VI are patentably distinct because the oligonucleotide may be used to detect the GluR7 allele while the transgenic non-human animal may be used as an *in vivo* model of disease. The protocols and reagents required for using oligonucleotides and transgenics are materially distinct and separate. The oligonucleotide does not require the transgenic and the transgenic does not require the oligonucleotide.

Groups III and IV are patentably distinct because the antibody may be used to isolate the GluR7 receptor while the method of administering a compound may be used to treat disease associated with GluR7. The protocols and reagents required for using antibodies are materially distinct and separate than those required for treating disease. The antibody does not require administering a compound and the method of administering the compound does not require the antibody.

Groups III and V are patentably distinct because the antibody may be used to isolate the GluR7 receptor while the method of contacting a cell expressing GluR7 receptor with a compound may be used to identify compound capable of treating disease associated with GluR7. The protocols and reagents required for using an antibody are materially distinct and separate than those required for identifying compounds capable of treating disease. The antibody does not require identifying a compound and the method of identifying the compound does not require the antibody.

Groups III and VI are patentably distinct because the antibody may be used to isolate the GluR7 receptor while the transgenic non-human animal may be used as an *in vivo* model of disease. The protocols and reagents required for using antibodies and transgenics are materially distinct and separate. The antibody does not require the transgenic and the transgenic does not require the antibody.

Groups IV and V are patentably distinct because administering a compound to a subject may be used to treat disease associated with the GluR7 receptor while the method of contacting a cell expressing GluR7 receptor with a compound may be used to identify compound capable of treating disease associated with GluR7. The protocols and reagents required for administering a compound to a subject are materially distinct and separate than those required for identifying the compounds using cells expressing GluR7. The method of administering the compound does not require the method of identifying a compound using cells expressing GluR7 receptor and the method of identifying the compound does not require administering the compound.

Groups IV and VI are patentably distinct because administering a compound to a subject may be used to treat disease associated with the GluR7 receptor while the transgenic non-human animal may be used as an *in vivo* model of disease. The protocols and reagents required for administering a compound to a subject having a disease associated with the GluR7 receptor and transgenics are materially distinct and separate. The method of administering the compound to a subject does not require the transgenic and the transgenic does not require the method of administering the compound.

Groups V and VI are patentably distinct because contacting a compound with a cell expressing GluR7 receptor may be used to identify a compound capable of treating disease associated with the GluR7 receptor while the transgenic non-human animal may be used as an *in vivo* model of disease. Contacting a compound with a cell in Group V is performed *in vitro* as indicated by the term "incubated" which implies contacting the compound and cell *in vitro*. The protocols and reagents required for incubating cells and a compound *in vitro* and for transgenics are materially distinct and separate. The method of identifying the compound does not require the transgenic and the transgenic does not require the method of contacting a cell and a compound.

Group IV, claims 22-28, are improper claims and cannot be properly restricted. The claims encompass administering any compound to a subject to treat disease. Administering specific compounds (such as DNA, antibodies, et al.) to treat disease are each restricted into their own group based on the compound being administered because each would be classified

differently, would have different modes of action and require different searches. However, in the instant case, applicants have not limited the claims to administering any specific compound. As such, a proper restriction cannot be done at this time.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER